EXHIBIT 1

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Assertions Of Deliberative Process Privilege By The Government To Prevent Witnesses From Answering Questions	
Robert Vito	
Vito 1 (346:14-347:15)	Q. Do you recall having any discussions at any time with anyone at OIG or HCFA about what a reasonable profit margin would be for albuterol sulfate? MR. NEAL: I'll object to the form. You can answer that to the extent that you don't disclose any communications that took place in entrance/exit conferences or other privileged settings. THE WITNESS: I think we had general discussions. BY MR. TORBORG: Q. What -- what do you remember about those discussions? A. That it was just, you know, discussions about what -- what should be a -- a markup. Q. What do you recall about what markup would be appropriate in those discussions? MR. NEAL: Object to the form. And my instruction stands. THE WITNESS: I -- I -- I don't remember all the details, but there were discussions about that, because we -- we believed that providers should be paid a fair price.
Vito 2 (436:6-439:22)	Q. So is it your understanding that the -- the -- the basic message that Ms. Min DeParle was -- is saying is we recognize that the acquisition cost for suppliers for this particular drug, albuterol sulfate, is a lot lower than the AWP, but by statute we are required to pay an amount based on AWP as published in Red Book and other price listings? A. That's – MR. NEAL: Objection as to form. MR. AZORSKY: Objection. THE WITNESS: That's what she said, yes. BY MR. TORBORG: Q. And do you recall having conversations like that with members of HCFA? MR. NEAL: I'll object to the form. You can answer that to the extent that you don't implicate any privileged conversations with HCFA personnel, such as those at entrance or exit conferences for your reports. THE WITNESS: Did we have discussions with HCFA people on this issue? BY MR. TORBORG: Q. Yeah. A. On this particular report, yes, we did. Q. Do you recall having conversations with the members of HCFA that they felt they were required to -- to use the prices in Red Book and other pricing compendia in reimbursing drugs? MR. NEAL: Objection as to form. You can answer that consistent – THE WITNESS: I think – MR. NEAL: -- with my previous instruction. THE WITNESS: Yeah, I think they used that. They -- they -- they -- they used those. I don't know if they used all of them, but they used at least one of them. BY MR. TORBORG: Q. My conversation was -- my question was: Do you recall having conversations with HCFA where they indicated to you that they understood they were required to use the prices in Red Book and other pricing compendia in determining reimbursement for Medicare Part B drugs? MR. NEAL: Objection as to form. You can answer that so long as you don't implicate any privileged conversations – THE WITNESS: Right. MR. NEAL: -- with HCFA personnel. THE WITNESS: I think it again depends on the time, because there was a regulation that said estimated acquisition cost, and then if they had that, they could have used that or they could use the other ones. But then I think there was a change in -- in the actual regulation, and it -- and it said that you should be using those. I know that as a pol -- as a policy, they used those documents to set prices.

	BY MR. TORBORG: Q. Do you recall conversations with HCFA where they said, well, we see your findings, Mr. Vito, but we have to pay based on AWP because that's what Congress told us we have to do? MR. AZORSKY: Objection. MR. NEAL: Objection as to form. BY MR. TORBORG: Q. Something to that effect? MR. NEAL: Objection as to form. And you can answer that consistent with my previous instruction on privileged communications. THE WITNESS: Something similar to that, but we -- we -- we suggested that there was other opportunities for them to take price reductions and to utilize those other options.
Vito 3 (452:14-453:3)	Q. And do you recall having conversations after the Balanced Budget Act of 1997 or after January 1, 1998 about the fact that HCFA felt it was required to pay based upon the published prices in Red Book and other price listings? MR. NEAL: I'll object to the form. And again instruct you: You can answer that so long as you don't disclose the substance of any communications that took place in privileged settings, such as the exit or entrance conferences. THE WITNESS: I'm -- I'm -- I -- I think we probably did.
Vito 4 (491:19-493:20)	BY MR. TORBORG: Q. Did you have a more global discussion about generic drugs in general and what was causing many of those drugs to sell at prices -- for there to be such a difference between the actual selling price and average wholesale prices? MR. NEAL: I'll object to the form and just instruct the -- Instruct you that you can answer that question consistent with my previous instructions not to disclose the substance of any communications that took place at entrance or exit conferences with CMS. THE WITNESS: Could you restate the question now? I -- I -- I totally – MR. NEAL: That's a lengthy instruction. THE WITNESS: Yeah. MR. NEAL: I apologize. BY MR. TORBORG: Q. Did you have any global discussions about generic drugs in general with CMS – A. Well – Q. Let me finish. A. I'm sorry. Q. -- regarding the fact that there was a -- a larger difference between the actual selling prices to providers and the published average wholesale price? MR. AZORSKY: Object to the form. MR. NEAL: I object to the form as well. And you heard my previous instruction. THE WITNESS: I -- I -- I believe that we -- our reports spoke for themself, in that there were some products that were generics that were -- that had that difference, and there were also some brand name products that had that difference as well. And, again, it was each -- each report stood on its own merit. Albuterol, I think that you showed me we probably did at least -- I saw at least four of the ones that we did, and they were generic drugs, and we were showing what was going on in that. In addition to that, I -- I – the excessive Medicare reimbursement report, I believe that also pointed out some problems both with the brand name products and the generic products.
Vito 5 (607:22-608:13)	Do you recall comments to the effect, Mr. Vito, from HCFA officials that claimant -- that payment for services was built into the fee schedule for prescription drugs? MR. NEAL: I'll object to the form. And just instruct you that you can answer that to the extent you don't implicate any privileged communications with HCFA officials. THE WITNESS: I -- I -- I am not certain on -- on that. I -- I -- I -- I don't know for sure if that's what was discussed or if they said that the cost is -- is -- that the reimbursement is the reimbursement, so I don't -- I -- I don't recall.
Vito 6 (611:20-612:11)	Q. And do you recall any conversations with HCFA relating to the Medicare side about whether or not the payment for ingredient cost would subsidize inadequate payment for services?

	MR. NEAL: You can answer that consistent with my previous instruction on privileged communications with HCFA officials. THE WITNESS: I think it – MR. AZORSKY: Objection to form. THE WITNESS: I think it was -- in our later reports, we mention that in the conclusion or the recommendation, so I think there was – that was definitely, I believe, in a public document from the OIG.
Larry Reed	
Reed 1 (298:1-8)	Q. Okay. And was that possibility of using the AMP data in deciding whether or not to approve state plans something that HCFA considered? MS. MARTINEZ: Objection. To the extent that that question would go to internal deliberations about whether or not to use it, you're instructed not to answer.
Reed 2 (312:6-313:22)	MR. TORBORG: What I'm going to do is ask a couple questions, have you object, have you tell me what grounds you're objecting upon, and we'll go from there. How's that? First question, Mr. Reed, for you is this: Did you have discussions within HCFA about whether or not AMP data could be shared with the states? MR. DRAYCOTT: You can answer that question -- if you can answer that question yes or no, you may answer it. THE WITNESS: Going back to the start of the program discussing having AMP shared with the states, we did have those discussions. BY MR. TORBORG: Q. Okay. Can you tell me about those discussions? MR. DRAYCOTT: And you can't -- you may -- you're instructed not to answer to the extent that those discussions were deliberations that ended up with the adoption of a policy on that issue. THE WITNESS: Okay. Could you repeat the question? BY MR. TORBORG: Q. Tell me about the discussions you had within HCFA about whether or not AMP data could be shared with the states. A. Those discussions led us to conclude that it was better to share unit rebate amounts with the states. Q. And why did you conclude that? MR. DRAYCOTT: And you may answer that question except to the extent it will reveal either the content of the deliberations or communications with agency counsel. So you can only -- can you answer that question without revealing either of those? THE WITNESS: No
Reed 3 (420:6-421:16)	BY MR. TORBORG: Q. Do you recall discussions within HCFA about the fact that Congress did not want pharmacies to be making less money in treating Medicaid patients until December 31, 1994? MS. MARTINEZ: Objection, form, and also objection to the extent that it asks for internal deliberations. You can answer to the extent that you're not revealing any internal deliberations that lead to a decision. THE WITNESS: Okay. So I can answer yes, that there were discussions? MS. MARTINEZ: If it didn't lead to a decision, yes. MR. TORBORG: I think from now on, Annie, I'd like you to just say objection, deliberative process privilege. I think he's been given enough direction on how to deal with this issue. I think there's a question pending. MS. MARTINEZ: I think he answered it. BY MR. TORBORG: Q. What was the answer? MS. MARTINEZ: Yes. BY MR. TORBORG: Q. You do recall discussions about that? A. About this provision? Q. Can you tell me about those discussions? MS. MARTINEZ: Objection to the extent that you're asking for privileged communications.

	THE WITNESS: No.
Reed 4 (488:6-489-20)	Q. Let me ask you to flip to the next page, Bates page ending 552, second sentence under the section "Scope." OIG wrote, "Our review was limited to ingredient acquisition costs and do not address other areas such as the effect of Medicaid business as a contribution to other store sales." I'd like to stop there. Do you recall that being an issue that was discussed at HCFA, the contribution of – to other store sales of Medicaid business? MS. MARTINEZ: Objection, form. THE WITNESS: I believe this may have been an issue that we addressed in the notice of proposed rulemaking for the Deficit Reduction Act. BY MR. TORBORG: Q. How so? A. I think it was looking for a discussion of -- if I remember correctly, it was a discussion of Medicaid pricing versus what that pharmacy might earn in other store sales. Q. HCFA was looking for comments from the industry on that; is that right? A. That's correct, not only industry, but from any commenter. Q. And do you recall the results you received on that question? A. No, not offhand, I don't. Q. Do you recall that topic being discussed prior to HCFA's looking for comments in that in connection with the DRA of 2005? MS. MARTINEZ: Objection, privilege. You're instructed not to answer, to the extent that there were discussions leading up to the issuance of that proposed rule.
Reed 5 (491:21-494:7)	BY MR. TORBORG: Q. And then this sentence also -- OIG also says other areas they do not address included "the cost to provide professional services other than a -- other than dispensing a prescription, such as therapeutic interventions, patient education and physician consultation." Do you have an understanding of what those things are about? A. I think I have a general understanding of those -- of that topic. Q. And what is your general understanding of that topic? A. From this, the part of the sentence that you read me, that they looked only at the dispensing -- the cost of dispensing a prescription and did not look at these other services. Q. And do you recall discussions in your current HCFA about the cost of pharmacies to provide professional services other than dispensing prescriptions, such as therapeutic intervention, patient education and physician consultation? Do you recall discussions about that? A. Yes. Q. Can you tell me about those discussions? MS. MARTINEZ: Objection, privileged. To the extent that those discussions were done in anticipation of a decision or a proposed rulemaking or another decision at HCFA, you're instructed not to answer. Otherwise, you can answer. THE WITNESS: I can't answer. BY MR. TORBORG: Q. Because of the privilege issue? A. Correct. Q. Okay. What policy does that – do those deliberations relate to? A. There are policies -- and I don't remember the format that they're in -- on other services. It goes -- they go by different names, but other services that pharmacists provide that would be reimbursed separate from ingredient cost and dispensing fee. Q. Okay. So HCFA had discussions about a policy on that issue; is that fair to say? A. Yes. Q. Because of the instruction of counsel, I'm not going to be allowed to learn about those through questioning of you; is that right? A. Correct.
Reed 6 (519:9-521:15, 522:20-523:13)	Q. Did you have discussions about the significantly greater difference between AWP and acquisition costs for generic drugs as opposed to branded drugs? MS. MARTINEZ: Objection, form. MS. POLLACK: Objection, form. THE WITNESS: I believe we had those discussions.

	BY MR. TORBORG: Q. Who were those discussions with? MS. MARTINEZ: Objection, privilege. MR. TORBORG: We have to decide who the discussions were with before we can decide what privilege applies. MS. MARTINEZ: No, the discussions were within HCFA, and if they related to an anticipated decision by HCFA, then it would be privileged and then you would be instructed not to answer. If you had a discussion with somebody in the outside that's not related to a policy decision like that, you can -- you can answer. THE WITNESS: I can't answer. BY MR. TORBORG: Q. So you had discussions within HCFA about the significantly greater difference between acquisition costs and AWP for generic drugs as compared to branded drugs, correct? MS. MARTINEZ: Objection, form. THE WITNESS: We did have those discussions. BY MR. TORBORG: Q. And I'm not permitted to probe your memory here today because you've been instructed not to answer, correct? A. Correct. Q. And did your discussions have any impact on the amount at which HCFA approved state Medicaid plans for payment of drugs? A. I'm not sure I understand your question. Q. Okay. Let me see if I understand. We agree we had -- you had discussions within HCFA about the significantly greater difference between acquisition costs and AWP for generic drugs. MS. MARTINEZ: Objection, form. BY MR. TORBORG: Q. You had those discussions, right? MS. MARTINEZ: Objection, form. THE WITNESS: There were discussions. * * * BY MR. TORBORG: Q. The deliberative process privilege is supposed to apply to deliberations leading to a decision or a policy. A. Right. Q. I'm trying to decide – trying to figure out what decision or policy those discussions related to. A. The decision would be how to look at this and reviewing a state plan. Q. And whether or not to approve or disapprove the plan? A. That could be part of that decision. Q. Which would ultimately determine how much providers were paid for drugs, correct? A. Correct.
Reed 7 (529:4-532:20)	Q. I want to revisit some testimony we had during the last session. You indicated there were some discussions within HCFA about the differences -- the greater difference in AWP acquisition cost for generic drugs versus branded drugs, correct? MS. MARTINEZ: Objection to form. THE WITNESS: That there was HCFA discussion of that? Yes. BY MR. TORBORG: Q. And I asked you about those discussions, counsel asserted the deliberative process privilege. I then asked you what policy or decision that those discussions related to, and your answer was the decision would be how to look at this in reviewing the state plans, and I asked whether or not to approve or disapprove the plans, and you answered that could be part of the decision. My follow-up question for you, Mr. Reed, was what was HCFA's decision or policy? What was the final decision or policy that HCFA reached? MS. MARTINEZ: Objection to form. THE WITNESS: The decision that – and I'm not sure, HCFA may too broad of a term here, all of HCFA, but the decision was whether or not to revise regulations for looking at these types of ingredient costs or whether to issue policy instructions for that, and we didn't do -- we did not do either. BY MR. TORBORG: Q. So the decision was not to revise the ingredient cost regulations for -- what was the second? A. A policy guidance document. Q. And what was the rationale for that decision?

	MR. DRAYCOTT: You can answer, but only limit it to the decision itself. You should not answer to the -- with respect to -- to the extent the answer would reveal the deliberations that resulted in that final decision. MR. TORBORG: I just want to argue with counsel a little bit here before you answer, and that is, the deliberative process privilege does not apply to prevent us from understanding the rationale for the decision. We, I think, all agree on that, and if we don't agree, we can go get some case law, and I think we'll come to a quick agreement. So I am allowed to know what the rationale for the decision was. MR. DRAYCOTT: And he was so instructed just now. MR. TORBORG: Okay. MR. DRAYCOTT: You may state the rationale, but you have to be careful in just stating the rationale that resulted from the deliberations, not the deliberations themselves. THE WITNESS: Okay. The rationale basically is that there's a structure between CMS and the state Medicaid programs on how they operate their program and to what extent we intercede in -- in directly making them make changes to the program versus overseeing their program through the state plan process. BY MR. TORBORG: Q. And what about that structure led to your decision not to revise regulations or issue any other policy guidance? A. That there is a structure -- there is a structure in place, again, of how we relate to state Medicaid agencies. There are parts of the prescription drug program where we direct the states how to pay for drugs, or a maximum in aggregate to pay for drugs. There are other parts where the states make their determination of prescription drug payment policies – of prescription drug payment methodologies. Q. Any other further rationale you can provide? A. No, not at this point.
Reed 8 (556-557)	Q. Whose decision was it, Mr. Reed, on whether or not to approve or disapprove state plan amendments that did not call for a reimbursement methodology consistent with OIG's findings? MR. DRAYCOTT: Objection. You can answer if you can. THE WITNESS: I can't because I don't understand your question. Whose decision was it to do what? BY MR. TORBORG: Q. To approve or disapprove state plan amendments that did not provide a reimbursement methodology consistent with OIG's findings? A. The decision making authority for any state plan amendment rests with the Director of the Medicaid Bureau -- I'm not going to say that, because, at that point, it rests for some time -- for some time period with the regions and for some time period with the Director of the Centers for Medicaid & State Operations within CMS. Q. When was the -- when did that shift in responsibility occur? A. The shift occurred I believe in the early summer, late spring of 2002. Q. What caused that change in responsibility? A. I think there were some concerns that there may be differing interpretations in the regions to state plan amendments in this area. Q. Are those concerns that you had? MR. DRAYCOTT: Objection. To the extent -- you can answer, but only to the extent that you're not revealing your own participation in the deliberations that yielded the final policy decision about where authority would finally reside. THE WITNESS: Then I can't answer.
Reed 9 (560:3-561:11)	BY MR. TORBORG: Q. Did you have concerns yourself about whether or not there needed to be a change in who was approving state plan amendments? A. I can't answer that question. Q. Because it would reveal internal deliberations within HCFA? A. That's correct. Q. Your personal view? A. My personal view, if it was part of -- as I understand the instructions, if it was part of the decision making process, yes.

	Q. The fact that your personal views are involved in the decision making process doesn't automatically cover it -- make them covered by the deliberative process privilege. The deliberative process privilege covers the exchange of ideas, not necessarily your personal view. MR. DRAYCOTT: Objection. BY MR. TORBORG: Q. With that clarification, can you answer my question? A. But as I understand it, if my personal opinion were a part of the deliberative process because I expressed that opinion in reaching that decision, it would be covered. Q. And that's your understanding of the deliberative process privilege as conveyed to you by counsel? A. That's correct.
Robert Niemann	
Niemann 1 (79:2-15)	Q. You mentioned the Office of Inspector General. Do you recall having communications with the Office of Inspector General relating to drug payment policy issues? A. Yes. I'm -- yes, I know I did. Q. Who at OIG did you communicate with? A. Rob Vito. Q. What do you recall about your conversations with Mr. Vito? MS. OBEREMBT: I'm going to object to the extent that his conversations might contain deliberative process information. THE WITNESS: His findings, more than anything.
Niemann 2 (190:16-191:19, 197:3-21)	Q. Okay. Was there anybody within the agency who preferred to stay with AWP rather than go to EAC in your memory? MS. OBEREMBT: Objection to the extent you're asking him about deliberative process conversations. THE WITNESS: So what do I do? MS. OBEREMBT: Why don't we take a break and let me find out what he was going to say. * * * MS. OBEREMBT: Chris, I understand your question to be asking him about discussions he had with others at CMS about what the drug policy should be. MR. COOK: Yes. MS. OBEREMBT: So on that basis, I'm going to instruct him not to answer because it does go to deliberative process * * * BY MR. COOK: Q. And were there individuals who advocated for staying with the average wholesale price? MS. OBEREMBT: I'll direct you not to answer that on the grounds of deliberative process. MR. COOK: So I can't get the foundation of whether there were individuals who took that position? MS. OBEREMBT: That's right. Because that goes to the substance of the discussions. Your previous went to whether or not there were discussions. Now you're getting into the substance, so I have to object. BY MR. COOK: Q. Were there individuals who advocated using the estimated acquisition cost? MS. OBEREMBT: Objection. Grounds of deliberative process. I'll instruct you not to answer.
Niemann 3 (198:19-200:19)	Q. In any of these discussions, do you recall any participant ever expressing to you the belief that by paying average wholesale price, the Medicare program was reimbursing physicians at their actual acquisition cost? MS. OBEREMBT: Objection on the grounds of deliberative process. I'll instruct you not to answer. BY MR. COOK: Q. Has anybody ever in your time at HCFA expressed to you the belief that average wholesale price is a reliable indicator of the acquisition cost to physicians for drugs? MS. OBEREMBT: I'm going to object to the extent you're asking him about conversations he

	had that involve deliberative processes of the agency. I'm going to instruct you not to answer that, too. BY MR. COOK: Q. In any of these conversations relating to the possibility of abandoning AWP and going to estimated acquisition cost, did any of the individuals that you've described ever raise concerns about what the consequences would be to beneficiaries' access to care or other program goals of going to EAC? MS. OBEREMBT: Objection on the grounds of the deliberative process privilege. I'll instruct you not to answer. BY MR. COOK: Q. What position did you take about using average wholesale price or the estimated acquisition cost? MS. OBEREMBT: Objection on the grounds of deliberative process. I'll instruct you not to answer. BY MR. COOK: Q. Did politics ever play a role in the Medicare program's decision to continue to use average wholesale price rather than use estimated acquisition costs to establish its maximum allowable payment amount for drugs? MS. OBEREMBT: Objection to the extent you're asking him about discussions with agency personnel, where a policy decision was made. I have to instruct you not to answer that, too, I think.
Niemann 4 (200:20-202:4)	BY MR. COOK: Q. At various points in time between 1991 and 1997, without telling me about what discussions were made, is it fair to say the decision was made to stay with AWP and not go to estimated acquisition cost? A. Well, that was the stated, that was the regulation. Q. Well, the regulation allowed both. A. Oh, allowed both. Q. Yes. A. I'm sorry, would you repeat. Q. At various points in time, when the possibility of going from AWP to EAC was considered? A. Right. Q. In fact, HCFA continued to use AWP, correct? A. It did. Q. All right. After discussions relating to a possible change, and after it was decided to remain with AWP, did you ever have any discussions with any other personnel at HCFA about the decision that had already been made to stay with AWP, and whether that was a good idea? MS. OBEREMBT: Objection, because again I think you don't have a specific point demarcated. And his post policy discussions may be predecisional to subsequent policies. So I can't -- I'm going to object again on deliberative process, and instruct you not to answer.
Niemann 5 (204:11-205:10)	Q. Right. Did you or anybody else from HCFA in these conversations with staffers on the Hill ever advocate a change in the methodology away from AWP? A. Yes. Yes. Q. Why? MS. OBEREMBT: Objection. That goes to a deliberative process issue, since you're asking him why they would have expressed that opinion to the staffers. MR. COOK: So the decision was whether to talk to Congress? MS. OBEREMBT: You can ask him what was said to the staffers, but you can't ask him why that was said, because that does go to deliberative process information, okay? MR. COOK: Just so I understand and I've got the record straight, exactly which decision is that deliberation predecisional to? MS. OBEREMBT: To decisions made within the agency to either continue with the existing policy or to proceed with change in policy.
Niemann 6 (209:16-210:7)	Q. Other than Congress, were there any other individuals outside of HCFA with whom you discussed the issue of whether the Medicare program should use some methodology other than AWP to establish allowable amounts for prescription drugs?

	A. If you consider Rob Vito of the IG – is that HCFA? I mean, I don't know. I might have talked about it with him. Q. What did you discuss with Mr. Vito? MS. OBEREMBT: I'm going to object on the grounds of deliberative process. I'm going to instruct you not to answer about your conversations with Mr. Vito about whether HCFA should pursue a different policy.
Niemann 7 (216:8-219:13)	Q. But you would agree with me that HCFA was advised in 1992 that for at least these 30 facilities, Vancomycin was available at a median acquisition cost of $5 when its AWP was $19.17, correct? A. Yes. Q. Is this information that you would have expected to come to you had you been the program analyst in 1992 for physician administered drugs? A. Well, I think what you meant to ask is for ESRD related drugs, not physician administered drugs. Q. Well, first, I was saying if you had been the analyst -- MS. OBEREMBT: Let him finish. BY MR. COOK: Q. I'm sorry. A. This would have been more likely to come to me as the ESRD reimbursement person. But 4 actually, either way, it probably would have come to both of us. It would have come to people who promulgated the proposed rule and it might have come to me as well. Q. And although you have no specific memory of it, is this something that you would have expected that you would have reviewed carefully when it came to you? A. Yes. Q. Did you take any action with respect to reimbursement for Calcijex, Inferon or Vancomycin as a result of receiving this report, to your memory? A. I don't remember that we did. Q. Do you know whether anybody within HCFA considered taking any action with respect to reimbursement for any of these drugs as a result of receiving this report? * * * * MS. OBEREMBT: Chris, do you think you could rephrase the question to ask whether he knows if anybody took any action? MR. COOK: Well, I know nobody took any action. I actually want to know whether they discussed taking any action and decided not to. MS. OBEREMBT: Then I have to object based on deliberative process, and I'll instruct you not to answer.
Niemann 8 (272:12-17)	Q. Was there ever any consideration of using the information available from the federal supply schedule to adjust Medicare reimbursement levels? MS. OBEREMBT: Objection. On the grounds of deliberative process, I'll instruct you not to answer.
Niemann 9 (478:4-479:21)	Q. Do you know why it was that CMS issued Exhibit Abbott 184? A. Usually that's in the program memorandum itself. Is it not in there? Oh, the purpose, thank you, is to provide you with an alternative source of average wholesale price data. Q. As counsel pointed to you, that certainly is the stated purpose of the program memorandum. I'm asking you why, the motivation for issuing the program memorandum. MS. OBEREMBT: I'm going to object to the extent you're trying to get at deliberative process information. If you can answer without referring to something covered by the deliberative process privilege, please do so. THE WITNESS: I don't think I can. MS. OBEREMBT: Okay. MR. COOK: Could I get the foundation for the deliberations that aren't being revealed? MS. OBEREMBT: You asked him the motivation. MR. COOK: Uh-huh.

	MS. OBEREMBT: Unless it's stated in this document, I don't think he can discuss internal deliberations within the agency that aren't reflected in this document. BY MR. COOK: Q. Are there internal deliberations relating to this document that you would have to reveal in order to answer my question? A. I think so. If it's not stated in here, then anything I know -- yes, yes. Q. Among who -- among whom did those deliberations take place? A. My chain of command and analysts in the Office of Legislation. Q. Anyone else? A. All internal. It would all have been HCFA people.
Niemann 10 (527:9-12)	Q. Did anyone within the agency oppose the issuance of transmittal AB-00-86 [concerning revised AWP information developed by Department of Justice and NAMFCU]? MS. OBEREMBT: Objection, calls for deliberative process.
Charles Booth	
Booth 1 (176:20-179:7)	Q. I mean, is it fair to say that in deciding what HCFA chose to pay for drugs reimbursable by Part B, that you would consider access to care for beneficiaries? A. I would hope. Q. And that if you picked a price point too low, it would impact access to care for beneficiaries, correct? MR. BREEN: Objection to form. MR. GOBENA: Also I'm going to instruct the witness the extent to which he needs to get into issues that are part of the deliberative process, I instruct you not to answer it, but if you can answer it otherwise, then please go ahead and answer. THE WITNESS: Well, I think that one of the objectives for at least my office at the time was not to adversely impact the quality or quantity of patient care. MR. COOK: Just so I know what he's not telling me, I don't quite understand when you tell him things that impact the deliberative process, what are you telling him not to tell me? MR. GOBENA: Well, to the extent – your questions are vague, so I'm not quite sure if you're asking about what gave rise to the '91 regulation, for example, that went into effect in 1992, and what considerations went into what was ultimately in that regulation. The extent to which you're trying to get into that, and it's not clear to me from your questions what you're trying to get into, I'm going to instruct him not to answer anything regarding discussions he had giving rise to the issuance of that regulation. Anything else outside of that, I think that's okay. MR. COOK: And just so the record's clear, if I ask Mr. Booth why HHS chose the methodology that they did that's published in the 1991 regulations, you'll instruct him not to tell me why the agency chose that methodology. MR. GOBENA: I'll instruct him not to answer that question because you're asking about the deliberative process, why their agency chose – the extent the agency chose to publish it and came to final decisions that reflected whatever you're looking at right there in front of you. MR. COOK: Okay, so just so I'm clear, it's your position that my ability to determine why the regulation stated 100 percent of AWP is limited to what the agency chose to publish in the Federal Register? MR. GOBENA: Chris, I think we've already briefed this issue of deliberative process. You've raised a larger deliberative process waiver argument and we've briefed it fully.
Booth 2 (191:2-21-193:1)	Q. You indicated to me that in discussions with Amgen, the possibilities of an AWP methodology or reasonable charge methodology were discussed. A. Yes. Q. I think I've asked you whether you can remember any other methodologies that you personally considered, and that these three are the only ones that you recall right now, correct? A. That's what I've said. Q. What I'd like to know is not restricting this simply to conversations with Amgen, could you describe for me what you considered in connection with reasonable charge?

	MR. GOBENA: I'm going to object and I'll have to instruct the witness not to answer to the extent that we're going -- that he's going to get into areas of deliberative process. The question as phrased, I don't know whether or not it would touch on discussions, deliberations that Mr. Booth had with any members of his staff, so – MR. COOK: Feel free to instruct him not to answer. MR. GOBENA: Okay. BY MR. COOK: Q. Mr. Booth, what factors did you consider in rejecting the reasonable charge in favor of the fee schedule for your recommendation to the administrator of HCFA? MR. GOBENA: Same objection, instruct the witness not to answer on the basis of deliberative process. BY MR. COOK: Q. You considered average wholesale price as another methodology, correct? A. Yes. Q. And you ultimately rejected that methodology in favor of recommending a fee schedule, correct? A. Yes. Q. What factors did you consider in choosing a fee schedule over an AWP-based methodology? MR. GOBENA: I'm going to object and instruct the witness not to answer on deliberative process grounds.
Booth 3 (204:8-205:22)	Q. Between 1989 and June of 1997, did HCFA change the composite rate that ESRD facilities were paid for treating Medicare beneficiaries? A. I don't remember. Q. Do you recall any discussions about whether the composite rate should be changed in light of profits the facilities were making on the drug component? MR. GOBENA: Chris, can I clarify? What discussions? Discussions with agency officials within the agency or – MR. COOK: With anybody at all. MR. GOBENA: Okay, I'll instruct you to not answer the question on deliberative process grounds the extent to which your answer would cover discussions within the agency. THE WITNESS: Then I can only tell you that there were end-stage renal facilities that came to see us and wanted an increase in the composite rate. BY MR. COOK: Q. Do you recall what response you gave to those facilities about whether you would give an increase to the composite rate? A. I recall very few increases in the composite rate. Q. Do you recall expressing to any of these facilities the notion that the composite rate was not being increased because of money being made on the drug component? A. Never. Q. Do you recall internal discussions in which the decision not to raise the composite rate was tied to money being made on the drug component? MR. GOBENA: I'm going to object and instruct the witness not to answer on deliberative process grounds.
Booth 4 (260:1-15)	Q. Let me ask it openly. Mr. Booth, what did you recommend should be the payment methodology in the final rule? MR. GOBENA: I'm going to object and instruct the witness not to answer to the extent it reflects deliberative process discussions. If there's some discussion -- if there's some way you can answer the question without getting into discussions you had within the agency about the final rule, you can answer the question. Otherwise I'll instruct you not to answer it. A. There were conversations with people outside the agency that suggested that for at least many individual drug codes, that a discounted AWP of 15 percent would be too harsh.
Bruce Vladeck	

Vladeck 1 (149:16-150:17)	Q. Do you recall anybody within HCFA who was under the belief that average wholesale price was an average of prices at which wholesalers sold drugs to customers? MS. BROOKER: Object to form. And I would just instruct the witness, just, you know, be mindful of not disclosing deliberations. THE WITNESS: Understood. A. I -- I think the most accurate way for me to answer the question -- I hope his response would be to say we did not believe -- I did not believe that it was an actually empirically-derived number in any form, that it was not necessarily, although it was possible, by chance, a reflection of what was occurring in the marketplace. Let me perhaps expand on that. Again, the analogy of the sticker price was one that had great influence in my thinking, and I would probably have expected, at that point, that there were always some poor suckers who were paying that price, just like there's always folks who end up paying list.
Vladeck 2 (177:5-178:7)	Q. I'm getting a little bit ahead of myself, but did you ever have discussions within HCFA about whether to change that reimbursement methodology for drugs such as this? MS. BROOKER: I'm going to instruct you to be mindful of not discussing internal pre-decisional deliberations on the record. A. We proposed, a number of times, to change the methodology, and, in fact, the proposal cited by the President, in his speech that we discussed earlier, was one that we had been advocating for -- within the administration since, I believe, about 1995. I think it is fair to say as well that I believed, as -- as far back as '95, that 85 percent of average wholesale price as a payment method was inferior to something closer than average acquisition cost, but that the administrative difficulties, and the potential administrative burden on physicians as a political issue, if not a real issue, made it likelier that we would be able to succeed with the legislative proposal still tied to AWP than one that went all the way back to its acquisition costs.
Vladeck 3 (183:3-185:5)	Q. You, as administrator of HCFA, considered alternatives to reimbursing at 100 percent of AWP. Correct? A. I don't know if we're getting into deliberative – MS. BROOKER: You should be mindful that you should not disclose any pre-decisional deliberative process. MR. COOK: I think it's going to be easier if you either direct him not to answer or let him answer, because I'm aware -- I'm a little leery of having the witness put in the difficult position of having to parse within his head – A. Well, let me -- I can say I was aware that conceptually there were alternatives to 100 percent of AWP. MS. BROOKER: Let me say you can state what your understanding was in your official capacity, and you can certainly state what the official policy was or the regulation, or what the statute was. You just cannot discuss pre-decisional deliberative conversations that you --that you had with others. THE WITNESS: I think I got that. Q. All right. Without revealing what the deliberations were, were there deliberations within HCFA about alternative methods for reimbursing to undiscounted AWP? MS. BROOKER: Objection to form. A. Extensive discussion. Q. Who -- who was involved in those extensive discussions? A. I don't know if that gets too deliberative. MS. BROOKER: You can say who was involved in deliberations. A. I would say that with the exception of the Medicaid folks, the list of people I enumerated earlier as experts I would have consulted on these issues would have been involved, whoever the deputy administrator was at the time would have been involved. And, again, probably other members of the staff of the office administrator probably would have been involved, as would additional staff in the Office of Legislation and Policy, in addition to the individuals I named earlier.
Vladeck 4	Q. How many alternatives were discussed?

(186:19-187:22)	MS. BROOKER: Objection. You should not discuss exactly what -- you should not discuss any of your deliberations, so you shouldn't talk about -- I mean, that's -- that's prohibited. MR. COOK: Well, are you instructing him not to answer? MS. BROOKER: You can talk about what official policy was. Q. In your internal deliberations at HCFA, how many alternative methods of reimbursement did 11 you consider? A. I couldn't say. I -- it's not a question of privilege. I couldn't say. Q. Okay. But within your internal deliberations, you did consider alternative methods of reimbursement. Correct? A. That is correct. Q. And, again, to -- to make the record as sharp as possible, what did you discuss in those deliberations? MS. BROOKER: Objection. You cannot discuss exactly what your deliberations were.
Vladeck 5 (372:4-18)	Q. Was there any discussion within HCFA that the creation of that dispensing fee was to make up, in some measure, for the lost profits from going from AWP to acquisition costs? MS. BROOKER: Objection. I would just instruct you to be mindful of not disclosing pre-decisional deliberations, and to just stick to policy. A. I don't know if this addresses the objection of the concern or not. I don't recall any specific discussion about that. My presumption was that as a policy it would have the effect similar to what you described, but I don't have any specific memory of this provision at all, frankly.
Vladeck 6 (498:22-499:13)	Q. Did you have discussions with others at HCFA prior to 1996 or 1997 concerning what the difference between AWP and transaction prices was for generics? MS. BROOKER: Objection. I would ask you also to be mindful of not discussing predecisional deliberative conversations. A. I think I can say that, again, in thinking about the average wholesale price and its relationship to anything else, it was not prior to then that I distinguished between generics and brand name drugs and, therefore, it's unlikely I would have had such a conversation at all.
Thomas Gustafson	
Gustafson 1 (175:15-22)	Q. . . . In your last answer, Mr. Gustafson, did you draw a distinction between a vendor payment program paying for or reimbursing for a drug? A. Mm-hmm. Q. Yes? A. I drew that distinction, correct. Q. What is the significance of that distinction? A. The principal payment policy, the Medicare program in general pays providers for services in almost all instances now at prices that are established in advance by the agency. This is thought of as different from a world of reimbursement, although that term is commonly used to cover what I've just described. But those of us who are immersed in the technical details of payment policy understand reimbursement to be a notion which would be more applicable in the old world of cost-based payments so that you are filling someone's purse after they have emptied it. The notion there is that the provider decides how much they should be paid as opposed to the program. So this distinction has mattered to the agency at different times. And in fact portions of the agency have been renamed in order to remove the remove the word reimbursement. Q. The current system in place for paying for part B drugs under Medicare part B is that a payment system or a reimbursement system? A. That's payment system. Q. Between 1991 and 2001, beginning with the promulgation of regulations in November 1991 through 2001 under Medicare part B for physician administered drugs, was that a payment system or a reimbursement system? A. As I understand it, you'd have to characterize it as payment system if you want to draw that distinction. In other words, the agency set, established, endorsed, acquiesced and used a set of

	payment rates that were known in advance, that were not differentiated by a particular provider, but which established a payment rate that carriers and FIs used in order to pay. Does that answer your question? Q. Yes, it does. Do you know what factors CMS took into account in determining what rate it should pay for part B covered drugs? MR. MAO: Tom, you should respond to the question again with the caveat to the extent that if your response requires you to reveal deliberations --
Gustafson 2 (189:7-190:11, 193:10-22)	Q. In December of 2006 could you have personally or through the offices of people with whom you worked explained why HCFA issued program memorandum AB-00-86 to Medicare carriers? MR. MAO: Objection, form. And also, again, you can go ahead and answer except to the extent that your response would require you to discuss internal deliberations that ultimately resulted in the guidance or directive that was published by the agency. A. If you are asking me could I have written more words on the page, then yes. Q. The second question of course would be would those words have been accurate? MR. WINGET-HERNANDEZ: Object to the form. A. Well, of course. I would have verified them. Therefore they would have been accurate. No. I'm sorry. I don't mean to be flip. Bumping in again to the question of I'm not recalling exactly what was in those two documents I referred to a moment ago, I'm not sure if it would have expanded one's understanding too much beyond what was there. And I believe, having discussed this previously with counsel, that I can't go beyond what I've said already without bumping into questions of deliberative privilege. * * * Q. Do you have any reason to believe that the agency could not have provided additional information in response to interrogatory number 15, leaving aside questions of privilege? A. I have no reason to believe they could not have insofar as the whatever is in this document did not fully cover the matter. And I don't know the answer to that question. And obviously deliberative privilege – deliberative process privilege -- excuse me -- enters this profoundly.
Gustafson 3 (257:11-258:16)	Q. Now, as I understand this particular statute, the Balanced Budget Act of 1997, was addressed to the agency, correct? A. The mandate typically runs to the Secretary, but allowing that precision, yes. Q. So the mandate runs to the Secretary who then delegates it to the agency, in this case it was HCFA, right? A. That's correct. Q. You said that the agency first must interpret the statute to determine what the mandate is, right? I'm sorry. You have to verbalize. Is that correct? A. I believe so. Yes. Q. How did the agency interpret the statute in this particular instance? A. I think it's well-known. We used average wholesale price in the Red Book as a reflection of average wholesale price as called for by the statute. Q. Who made the decision to interpret the statute in that manner? MR. MAO: You can answer except to the extent that it reveals deliberative process and deliberative discussions that they had internally. MR. AZORSKY: Objection to form. THE WITNESS: I don't think I can say anything on that subject without invading deliberative process questions.
David Tawes	
Tawes 1 (88:17-90:4)	Q. Do you recall the names of the program specialists who were involved in exit conferences relating to reimbursement of drugs? A. Linda Abbott, Sara Craren, Linda Frisch, Lisa Foley, Bambi Straw. Q. In your discussions with CMS, have they ever expressed frustration to you about drug reimbursement?

	MR. NEAL: I'm going to instruct the witness not to answer that question and put an objection on the record. MR. TORBORG: What's the basis of the objection? MR. NEAL: He's mentioned that his conversations with CMS personnel have taken place at exit and entrance conferences. We believe those conferences are integral to the deliberative process privilege. They are predecisional discussions with agency personnel relating to policy development, and as a result, we've asserted a privilege over the subject of those conversations. Your last question, I believe, would necessarily implicate those conversations. BY MR. TORBORG: Q. Without telling me the specific words that were said at these conferences, can you tell me your understanding of whether or not they were frustrated? MR. NEAL: I'm going to instruct the witness not to answer, so. That would reveal the substance of the communication, so my objection stands.
Tawes 2 (180:21-182:18)	Q. Did you have any discussions with individuals at CMS about the large percentage differences in the -- in the prices for generic drugs between actual acquisition cost, as shown in catalogs, versus published AWPs? MR. NEAL: I'm going to object to the question. I'll instruct you not to answer to the extent that those -- your answer would reveal communications that took place in the context of entrance or exit conferences with CMS personnel. THE WITNESS: Not outside of entrance or exit conferences. BY MR. TORBORG: Q. Do you recall having the discussions at all? MR. NEAL: I'm going to instruct the witness not to answer that question. MR. TORBORG: Can I ask him whether, without divulging specific communications, if he recall the discussions happening at all? MR. NEAL: The problem is, the discussions you're talking about involve a specific substance area. MR. TORBORG: That I think is important to the case; that's why I'm asking about it. MR. NEAL: That may be, but, you know, that -- that doesn't play into our privilege --privilege assertion, so... MR. TORBORG: So what you're saying, in essence, is regardless of how important it may be to my defense, you're still going to assert the privilege, no matter what? MR. NEAL: You can characterize it however you want to. I mean, the fact is, this is an important governmental privilege, and we're going to assert the privilege in this case. We have motions pending on -- you know, on this matter as we speak, and the Court will presumably resolve it for us. MR. TORBORG: Okay. Hopefully this will be of assistance.
Tawes 3 (264:16-268:1)	Q. Did you have discussions with anyone at CMS about why it was that CMS was not adding drugs to the Federal Upper Limit List that should have been added to the FUL List? MR. NEAL: Objection. You can answer that question so long as you don't disclose the contents of any conversations that took place during exit or entrance conferences. THE WITNESS: The conversations were all in entrance and exit conferences. BY MR. TORBORG: Q. Well, let me see if I can ask this. Did CMS officials at the entrance and exit conferences explain to you why it was that drugs were not being added timely to the Federal Upper Limit List? MR. NEAL: I'm going to instruct you not to answer the question. It gets into the substance of their – MR. TORBORG: Just a yes – MR. NEAL: -- topics – MR. TORBORG: -- or no question. MR. NEAL: Answering that question yes or no would reveal the contents of the communications, so... MR. TORBORG: It wouldn't reveal -- it's just a -- the broad general topic, whether it was discussed. MR. NEAL: It's on the borderline, but I'm going instruct him not to answer at this time.

	BY MR. TORBORG: Q. Other than a lack of resources, did HCFA provide any other explanations as to why drugs were not being added to the Federal Upper Limit List? MR. NEAL: Objection. You can answer that to the extent that you don't reveal the substance of any communications that took place during entrance or exit conferences with CMS. THE WITNESS: Outside of those conferences, anything -- any explanations that they came up with would have been in their comments to the reports. BY MR. TORBORG: Q. Let me see if I can ask that again. Other than a lack of resources at CMS, did HCFA provide any other explanations as to why drugs were not being added to the Federal Upper Limit List? MR. NEAL: I'll object to the question. And then you can answer that to the extent that you don't reveal the substance of communications that took place at entrance or exit conferences with CMS. THE WITNESS: Again, without going back to their official comments to the report, I mean, that's the extent outside of entrance and exit conferences. BY MR. TORBORG: Q. At the entrance and exit conferences, did CMS provide any explanations, besides resource-based reasons, why drugs were not being added to the FUL List? MR. NEAL: I'm going to instruct you not to answer the question. MR. TORBORG: Just a yes or no, he can't answer that? MR. NEAL: I'm going to instruct not to answer, yeah, it's -- my objection stands. MR. TORBORG: So there may be reasons why CMS did not add specific drugs to the FUL List that I'm not going to get to figure out? MR. NEAL: I mean, your question presupposes certain substantive communications from CMS and – MR. TORBORG: That's why – MR. NEAL: -- he's not – MR. TORBORG: -- I'm asking – MR. NEAL: -- going to disclose – MR. TORBORG: -- yes or no. MR. NEAL: He's not going to disclose those communications. MR. TORBORG: Well – MR. NEAL: The objection stands. I'm not MR. TORBORG: -- I'm not – MR. NEAL: -- going to debate – MR. TORBORG: -- trying to pre – MR. NEAL: -- with you right now, but, I mean, I -- the objection stands. You're asking about the substance of communications that took place and entrance and exit conferences, and, you know, we've asserted a -- a fairly broad objection over the substance of those communications. I don't think he can answer that even yes or no without disclosing the substance of the communication.
Tawes 4 (367:14-369:22)	BY MR. TORBORG: Q. What do you -- what do you recall about being asked to look at the dispensing-fee issue? A. In converse -- in conversations with CMS, them asking how much it really cost physicians -- I'm sorry -- how much it really cost the pharmacies to dispense the drugs and what services they're -- they're providing for those dispensing fees. Q. And just to back up a step, what is a dispensing fee? A. A dispensing fee is a fee paid with each prescription filled by a pharmacy. Q. Is the dispensing fee supposed to include a level of profit? MR. NEAL: Objection as to form. THE WITNESS: I am not sure about the -- about what it's supposed to include. BY MR. TORBORG: Q. With whom did you have these conversations? MR. NEAL: Let me just instruct you to answer that question consistent with my previous instruction. You can discuss this so long as you don't implicate essentially privileged communications at entrance and exit conferences. THE WITNESS: I don't recall exactly who was at the meeting. It would have been someone that I mentioned earlier as folks that I had met with, but I can't remember specifically who was there.

Tawes 5 (395:8-396:1)	Q. Do you recall any discussions with OIG or HCFA of what would happen if CMS changed the way it reimbursed for drugs? MR. WINGET-HERNANDEZ: Objection to form. MR. NEAL: I'll object to the form as well. You can answer that question to the extent that your answer would not divulge any privileged communication. THE WITNESS: In various conversations, I know that especially in the pharmacy area, not necessarily in the physician area, that there -- and that's why we had conversations about dispensing fees -- that CMS wanted to ensure that -- that beneficiary access wasn't inhibited based on any -- based on any cost reductions.
Tawes 6 (400:5-20)	Q. Have any of the conversations you've had with CMS relating to those reports discussed the access issue? MR. NEAL: I'll instruct you not to answer that question to the extent that it will require you to divulge privileged communications with CMS. THE WITNESS: Outside of entrance and exit conferences, there were a few discussions about how Federal Upper Limits were calculated and concerns that sometimes that the lowest price available -- or the lowest price listed in compendia wasn't accurate and not available to --to all pharmacies, and, therefore, setting the Federal Upper Limit amount based on that price could lead to access issues.
Tawes 7 (489:12-490:4)	Do you recall any conversations at any time, Mr. Tawes, regarding the ability of CMS to share AMP data with states? A. Yes. Q. Okay. Tell me what you recall about those conversations. MR. NEAL: I'll just instruct the witness: You can answer that question to the extent that your answer would not implicate privileged communications that you may have had. THE WITNESS: Simply a difference of opinion between CMS and some of the folks in Region 5 OIG, and I would assume O -- the OIG in general, as to whether CMS could provide AMP data to states.
Linda Ragone	
Ragone 1 (330:11-332:14)	Q. Did you ever discuss with anybody at HCFA what they thought was an appropriate amount of reimbursement? MR. NEAL: I'm going to object to the question. In fact, I'm going to instruct you not to answer to the extent that that would reveal any communications that took place at exit or entrance conferences. You've stated that you didn't – you don't have any recollection of those conferences. If you can answer the question without referring to any communications that took place there, you can answer the question. THE WITNESS: Would you repeat the question again, please? BY MR. COOK: Q. Sure. MR. NEAL: That was a lengthy objection. I apologize. There are privilege concerns. BY MR. COOK: Q. Did you ever discuss with anybody at HCFA what HCFA believed would be an appropriate amount of reimbursement for drugs under Medicare Part B? A. I don't remember if we discussed that at the entrance and exit conferences.
Ragone 2 (369:19-370:11)	Q. Any reason to believe that any of the sentiments expressed in the entrance and exit conferences for this report varied from the official responses given by Ms. Min DeParle in this memo? MR. NEAL: I'm going to object to the question and instruct you not to answer. BY MR. COOK: Q. Ms. Ragone – MR. MERKL: You're not going to let her answer that yes or no? MR. NEAL: Answering it yes or no would possibly implicate the substance of communications that she had in an exit conference concerning this report.

Ragone 4 (480:20-484:15)	Q. As of 2004, was Medicare still using AWP to base its Medicare Part B drug reimbursement? A. I don't remember what the time period was when it changed to – Q. Can you give me a rough? After 2000? A. Yes. Q. After 2002? After 2001? A. I think after 2002. I'm not quite sure when the legislation was enacted. Q. So whenever the legislation was enacted, perhaps for as many as five years after receiving the conclusions of this report, Medicare Part B continued to pay, for the 22 drugs reviewed in this report, based upon AWP, correct? MR. DRAYCOTT: Objection. THE WITNESS: Based upon, I guess, starting in 1998, they paid AWP minus 5 percent. BY MR. COOK: Q. But still based upon the AWP? A. Correct. Q. Did you ever have an argument with anybody at HCFA about the wisdom of doing that? MR. DRAYCOTT: Objection. THE WITNESS: I'm not -- I don't know if I would call it an argument. We've certainly had discussions during exit conferences about the fact that a different pricing methodology might be appropriate. BY MR. COOK: Q. What do they say about that? MR. DRAYCOTT: Objection. Instruct you not to answer. BY MR. COOK: Q. I know you're going to be instructed not to answer, but I do have to put the questions on the record, Ms. Ragone. So let me get this straight. You sit down in a room, at a conference table like this with folks from HCFA; you tell them that AWP exceeds acquisition costs, as defined in the report, by up to ten times, right? A. Yes. Q. You tell them that the OIG recommends that they stop paying that high an amount for prescription drugs, right? MR. DRAYCOTT: Objection to the extent that you're asking for the contents of her communications to HCFA during the exit conference. MR. COOK: If you'd just instruct her not to answer. Are you instructing her not to answer? MR. DRAYCOTT: I am. BY MR. COOK: Q. So you make whatever communications you do to HCFA in these exit conferences – MR. DRAYCOTT: Objection. BY MR. COOK: Q. -- after giving them a copy of this report, right? MR. DRAYCOTT: Objection. And you're instructed not to answer. BY MR. COOK: Q. And you make your recommendations, correct? MR. DRAYCOTT: You can answer that question. THE WITNESS: During the exit conferences, we will tell them the findings and recommendations. Q. And you encourage them, that is, officials at HCFA, to reimburse prescription drugs based upon something other than the published average wholesale price? MR. DRAYCOTT: Objection. You're instructed not to answer. BY MR. COOK: Q. And, in fact, you do so heatedly, correct? MR. DRAYCOTT: Objection. And you're instructed not to answer. BY MR. COOK: Q. And they respond? MR. DRAYCOTT: You can answer whether or not they responded. THE WITNESS: If they have comments, they will respond when we provide the findings and recommendations. BY MR. COOK: Q. Did they explain why HCFA continued to pay based upon AWP, notwithstanding the fact that HCFA knew average wholesale price could exceed acquisition cost by as much as ten times? MR. DRAYCOTT: You can answer as to whether or not they responded without revealing the response, if you remember. THE WITNESS: I believe that they stated why they were using the reimbursement strategy they were using at that time.

	BY MR. COOK: Q. And what was their explanation? MR. DRAYCOTT: Objection. And you're instructed not to answer. BY MR. COOK: Q. Why do you believe HCFA continued to use average wholesale price to pay for Medicare Part B drugs after you issued this report in December 1997? MR. DRAYCOTT: Objection. And you're instructed not to answer to the extent your belief is based on communications from HCFA during an exit conference. BY MR. COOK: Q. I'll let you work out that metaphysical problem. A. I -- I believe – MR. DRAYCOTT: Well – THE WITNESS: -- that the – MR. DRAYCOTT: Let me ask you: Can you answer that question without revealing the content of communication from HCFA during the conference? THE WITNESS: I believe I can. I believe I can. MR. DRAYCOTT: Okay. THE WITNESS: I believe that the level of people that we were talking to believed that the regulations or legislations were set for payment at a certain place and that that's what Medicare was bound to reimburse at.
Amy Bassano	
Bassano 1 (85:8-87:21)	Q. Okay. Do you know if any other options aside from basing payment for Part B drugs on AWP were considered from the period 1991 through 2001? THE WITNESS: Should I answer? MR. DRAYCOTT: The answer is just -- you asked the question is she aware. Q. Are you aware, were there any other options considered? MR. DRAYCOTT: You can answer that yes or no. A. 1991 to 2001? I believe there may have been. Q. And is this based upon your personal knowledge? A. No. Q. Based upon your review of historical documents? A. No. Q. What is it based on? A. Conversations with other people. Q. Conversations with people who worked with CMS at the time? A. Yes. Q. And they said other options aside from AWP were considered? A. Yes. Q. What were those options? MR. DRAYCOTT: Objection to the -- I mean, what is the context in which you're asking this? I mean, if you're talking about -- if you're going through internal deliberations within CMS policy making areas, such as the Office of Legislation where Ms. Bassano worked then I'd instruct her not to reveal the content of those deliberations within OL to the extent they were before developing a policy regarding reimbursement methodology. You've asked a very broad question. So I'm going to object to the question based on its breadth. I can try to instruct the witness to answer if she can with respect to non-privileged information or it may help to clarify the question. Q. Could you answer with respect to non-privileged information what other options aside from AWP were considered? A. No. Because I don't recall what actually ever was made public versus what was discussed internally and just had been considered. Q. In what perform was it considered? A. What does that mean? Q. Was it considered through policy papers? Was it considered just in discussions in meetings? MR. DRAYCOTT: If you can answer the question or if you have a recollection about the particular format –

	A. I don't know. No one ever specifically -- I don't know what formats it was considered in.
Bassano 2 (106:17-108:19)	Q. From 1991 through 2001 was CMS to your knowledge relying on AWP to reflect the actual market prices for drugs? MR. DRAYCOTT: Objection. But you can answer. A. I don't know. Q. Did you discuss that with anyone who was working at CMS on Part B issues from '91 through 2001? A. If it reflected actual market prices? Q. Yes. MR. DRAYCOTT: You're looking at me -- when you're looking at me is it because of a concern that you're being asked for privileged information or – THE WITNESS: Well, it's sort of what can I say about conversations I've had or didn't have with people at CMS. MR. DRAYCOTT: Well, it depends -- certainly what you can't testify about are conversations that would be covered by an attorney-client privilege or work product privilege such as conversations with office of general counsel or the Department of Justice. And you also can't testify as deliberative conversations that were directed at implementing or changing or considering the change to a policy. If Mr. Gabel's question -- I think -- it is a broad question -- is as to how something was implemented and how a policy was implemented, you can testify to that. So if it's the conversations that he's referring to -- and I understand why the question is difficult – MR. GABEL: Let me restate the question. MR. DRAYCOTT: Yeah. I think you need to be more specific in your question. MR. GABEL: I will. BY MR. GABEL: Q. Are you aware of anyone from the period of 1991 through 2001, anyone at CMS who relied on AWP to actually reflect the prices paid for drugs in the marketplace? MR. DRAYCOTT: Objection. But you can answer it if you can. A. I don't think anyone personally relied on the AWP or held it out and said this is the actual market price.